

The Office Action mailed March 6, 2006 has been carefully considered and this paper is responsive thereto. Claims 1-27 are pending in the application.

At page 2 of the Office Action, the Examiner provisionally rejected claims 1 and 2 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44 and 45 of copending application Serial No. 10/824,688.

Applicants request that this rejection be held until such time as notice of patentable subject matter has been received in the applications. Applicants will file an appropriate terminal disclaimer at that time if necessary.

At pages 3 and 6 of the Office Action, the Examiner rejected claims 1-17, 20, 21 and 23-27 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376) and separately rejected claims 18, 19 and 22 over the same reference. The basis for the rejections is that claimed delivery systems (capsules) are obvious in view of Gennadios which discloses gelatin-free capsules which contain kappa carrageenan. The Examiner stated that the delivery system and methods of the instant claims differ from the delivery system (capsule) and methods of Gennadios because the claimed gel film comprises kappa-2 carrageenan as opposed to kappa carrageenan used in Gennadios. The Examiner considered the substitution of kappa carrageenan with kappa-2 carrageenan to be obvious since, in the Examiner's view, both polymers are classified as kappa carrageenan and minor differences in the stability of gel strength between kappa-2 carrageenan and a similar amount of kappa-carrageenan/iota carrageenan combination purportedly does not show unexpected results.

Applicants traverse these rejections. The delivery systems of claims 1-17, 20, 21 and 23-27 comprise (i) a homogeneous, thermoreversible gel film, wherein the gel film comprises a film-forming amount of kappa-2 carrageenan and, optionally, at least one of a plasticizer, a second film former, a bulking agent and a pH controlling agent, and (ii) an active substance. The active substance can be an oral care agent, a breath freshening agent, an antimicrobial agent or other agent as set out in the specification. The methods of claims 18, 19 and 22 are limited to the preparation of the claimed delivery systems comprising thermoreversible, homogeneous, gel films comprising kappa-2 carrageenan and an active substance.

Gennadios discloses compositions useful for preparing gelatin-free capsules for oral administration of medicines, cosmetic or bath applications, or dietary supplements and methods

for preparing the compositions. The compositions are disclosed to contain 0.5 to 12% by weight of kappa carrageenan, where the kappa carrageenan comprises at least 50% by weight of all film-forming material in the composition. Gennadios discloses that part of the kappa carrageenan can be substituted by iota carrageenan (up to a maximum of 50% or 25% by weight of the kappa carrageenan), which, according to the patent, forms “softer” and more elastic gels.

Gennadios does not disclose or suggest: (i) homogeneous, thermoreversible, gel films comprising kappa-2 carrageenan, or (ii) an active substance incorporated therein.

Applicants explain that kappa-2 carrageenan has a different structure and different properties than kappa carrageenan (and iota carrageenan).

That is, as discussed at pages 4-6 of the specification, carrageenan is a commercially significant galactan polysaccharide found in red seaweed. All carrageenans contain repeating galactose units joined by alternating  $\alpha 1 \rightarrow 3$  and  $\beta 1 \rightarrow 4$  glycosidic linkages and are sulfated to widely varying degrees. The types of carrageenan may be distinguished, in part, by their degree and position of sulfation, as well as the seaweed from which they are obtained. For example, iota carrageenan has a repeating unit of D-galactose-4-sulfate-3,6-anhydro-D-galactose-2-sulfate providing a sulfate ester content of about 25 to 34%. Iota carrageenan can be obtained, for example, from *Eucheuma denticulatum* (also known as “*Spinosum*”). Kappa carrageenan has a repeating unit of D-galactose-4-sulfate-3,6-anhydro-D-galactose and is obtained, for example, from *Kappaphycus alvarezii* (also known as “*Eucheuma cottonii*”). In contrast, kappa-2 carrageenan is reported by R. Falshaw, H.J. Bixler and K. Johndro, *Structure and Performance of Commercial Kappa-2 Carrageenan Extracts*, Food Hydrocolloids 15 (2001) 441-452, and by H. Bixler, K. Johndro and R. Falshaw, *Kappa-2 carrageenan: structure and performance of commercial extracts II*, Food Hydrocolloids 15 (2001) 619-630 to be copolymers containing a certain amount of kappa repeating units (3:6-anhydroglactose (3:6-AG)) and iota repeating units (3:6-anhydroglactose-2-sulfate (3:6-AG-2-S)) covalently bound in the copolymer backbone and obtained from certain *Gigartinaceae* algae. The foregoing references (cited in this case in an IDS and attached hereto for the Examiner’s convenience) state that such kappa-2 carrageenans have distinctly different properties as compared to simple mixtures of kappa and iota carrageenans. Recent studies, such as those mentioned immediately above, have confirmed that kappa-2 carrageenans are copolymers containing kappa and iota repeating units covalently bound

(in certain ratios of kappa to iota moieties) in the copolymer backbone in clear distinction to physical mixtures of kappa and iota polymers.

As disclosed in the present specification, kappa-2 carrageenan has a molar ratio of 3:6AG-2S to 3:6AG content of 25 to 50%, iota carrageenan has a molar ratio of 3:6AG-2S to 3:6AG content of 80 to 100% and kappa carrageenan has a molar ratio of 3:6AG-2S to 3:6AG content less than that for kappa-2 carrageenan. For example, kappa carrageenan from *Eucheuma cottonii*, a commonly known and used seaweed source for kappa carrageenan, has a molar ratio of 3:6AG2S to 3:6AG content of less than about 10%; and iota carrageenan from *Spinosum*, a commonly known and used seaweed source for iota carrageenan, has a molar ratio of 3:6AG2S to 3:6AG content greater than about 85%. This means that kappa-2 carrageenan comprises a ratio of kappa (3:6-AG) to iota (3:6-AG-2-S) repeating units between 1.0 to 3.0:1, more particularly, 1.5 to 3.0:1 (more particularly depending on the desired application). The molar ratio of 3:6AG-2S to 3:6AG content of 25 to 50% holds in kappa-2 carrageenans regardless of its degree of modification and precursor content (e.g., mu and nu repeating units).

No references have been cited by the Examiner to suggest that kappa-2 carrageenans are sufficiently similar in structure to kappa carrageenan and iota carrageenan so as to lead to the conclusion that kappa-2 carrageenan would be expected to have similar properties as kappa carrageenan and iota carrageenan.

Indeed, as discussed at pages 7-9 of the specification, iota and kappa carrageenans were generally considered to be gelling carrageenans, whereas kappa-2 carrageenans were generally known to be weakly gelling. Kappa-2 carrageenan has much lower water gel strength than kappa carrageenan, iota carrageenan or physical mixtures of kappa and iota carrageenan. As a result, it would have been expected that such weakly gelling carrageenan would form weak gel films. To the surprise of Applicants, however, the opposite was found; kappa-2 carrageenan forms surprisingly strong gel films. This surprising film strength of kappa-2 carrageenan is considered to allow carrageenan molecular weight control in order to better balance process viscosity and required film strength for mechanical processing, such direction resulting in the capability to operate at lower moisture levels in the cast films while maintaining other essential film properties.

Examples of the presently claimed invention comprising kappa-2 carrageenan gel films are provided in the examples of the present application.

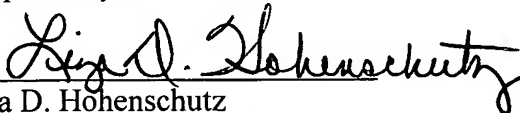
As set forth above, the Examiner has not provided any references demonstrating that kappa-2 carrageenan is structurally similar to kappa carrageenan (or iota carrageenan) or any references demonstrating that kappa-2 carrageenan is known to have similar properties as kappa carrageenan (or iota carrageenan). On the contrary, in view of the structural differences and differences in gelling property generally believed to exist between kappa-2 carrageenan and both kappa and iota carrageenans as noted above and the references cited herein and attached hereto, it is respectfully submitted that one skilled in the art would not have found the presently claimed invention, i.e., a delivery system comprising a thermoreversible, homogeneous, gel film comprising kappa-2 carrageenan and an active substance and methods for the manufacture thereof, obvious in view of the cited prior art. Additionally, unlike the claimed delivery systems, Gennadios provides no disclosure or suggestion of incorporating an active substance in the gel film itself. Accordingly, withdrawal of the rejections of claims 1-17, 20, 21 and 23-27, and 18, 19 and 22 as obvious under 35 USC 103 is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 10884-00018-US. A duplicate copy of this paper is enclosed.

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Respectfully submitted,

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